REMARKS

In view of the above amendments and the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 51-67 and 72-78.

Claim 51 has been amended to specify that the height of the chamber is less than about 0.5 mm. Support for this amendment may be found throughout the specification, e.g., at page 8, lines 11-13. The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as acquiescence to any objection or rejection of any claim.

The specification has been amended to include the sequence identification numbers at page 25 and to include the attached sequence listings as separately numbered page 42 after the abstract.

As no new matter has been added by the above amendments, the Applicants respectfully request the entry thereof.

OBJECTION TO THE SPECIFICATION

The specification is objected to on the grounds that documents have been improperly incorporated by reference. The Examiner objects to the language at page 15, line 8 and at page 21, lines 10-11 relating to relating to the incorporation by reference of all patents, patent applications and publications mentioned in the application. The Examiner asserts that the language "fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited references." The Applicants note that the documents cited in the instant application are incorporated by reference in their entirety and are not limited to specific portions or passages thereof.

In making this objection, the Examiner relies on *Advanced Display Systems*. As is demonstrated below, the Applicants respectfully submit that the cited case law cited in the Office Action is mischaracterized and does not, in fact, stand for the general principle alleged in the Office Action. Accordingly, the Applicants thus respectfully submit, as supported by the discussion below, that the instant situation is not analogous to that of *Advanced Display Systems, Inc.* Furthermore, the Applicants respectfully submit that the manner in which the documents of the instant application are incorporated by reference are proper and thus the documents cited in the present application are properly incorporated by reference in their entireties.

The Office Action relies on *Advanced Display Systems, Inc.*, to support a general proposition that the specification must identify specific portions of a document incorporated by reference. The

relevant issue in *Advanced Systems* concerned anticipation based not on a patent alone, but rather on the combination of the patent and the material potentially incorporated by reference therein. The issue thus was whether a magistrate judge committed legal error by instructing the jury to determine whether and what material was incorporated by reference into the patent. The court described generally the subject of incorporation by reference. In this description, the court noted " To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents. See *In re Seversky,* 474 F.2d 671, 674, 177 U.S.P.Q. (BNA) 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found")". It is this passage that the Office Action cites.

However, the situation of *In re Seversky*, the case cited in *Advanced Display*, is wholly different from the present situation. In the situation of *In re Seversky*, the Appellant attempted to incorporate by reference teachings of interest from a grandparent application. The parent application, was totally devoid of any reference to the teachings of interest, however the Appellant urged that the defect was cured because the grandparent disclosed the teachings and because the parent application is a continuation-in-part of the grandparent that disclosure was, *ipso facto*, incorporated by reference in the parent. In other words, the situation was one in which there was no "incorporation-by-reference" language whatsoever - a situation wholly different from the instant application which does include "incorporation-by-reference" language.

Accordingly, the Applicants submit that the documents cited in the instant application are properly incorporated by reference in their entireties. As such, the Applicants respectfully request the objection to the specification be withdrawn.

SEQUENCE RULES COMPLIANCE

The Examiner asserts that the application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(c) and (a)(2), but the application fails to comply with the requirements of 37 CFR 1.821 through 1.825. The specification at page 25 has been amended to include the sequence identification numbers.

Furthermore, the specification has been amended to include the sequence listing. The Applicants hereby certify that the enclosed Sequence Listing is being submitted under 37 CFR §§ 1.821(c) and (e) in paper and computer readable form (Compact Disk labeled 'CRF').

As required by 37 CFR 1.821(f), the Applicants hereby state that the content of the paper and computer readable copy of the Sequence Listing, submitted in accordance with 37 C.F.R. §1.821(c)

and (e) are the same. The Computer Readable Format (CRF), being submitted under 37 CFR §§ 1.52(e) and 1.824, is formatted on IBM-PC, the operating system compatibility is MS-Windows and the file listing is:

Seqlist.txt 1.0 Kb created June 1, 2004.

The Applicants hereby certify that the enclosed submission includes no new matter. The Sequence Listing was prepared with the software FASTSEQ, and conforms to the Patent Office guidelines. The Applicants respectfully submit that the subject application is in adherence to 37 CFR §§ 1.821-1.825.

REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 51-67 and 72-78 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

In making this rejection, the Examiner asserts that the specification lacks an adequate written description to support the breadth of scope for (1) the concentration of surfactant, and (2) the dimensions of the device. The Applicants respectfully traverse this rejection.

As described in the Applicants' previously submitted response, responsive to the Office Action dated September 8, 2003, the Applicants respectfully submit that the specification provides adequate written description with respect to the surfactant and the chamber.

As noted in the MPEP at section 2163.03 (emphasis added), "While a question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently (see, e.g., *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997)), there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed...Consequently, rejection of an original claim for lack of written description should be rare." As described in the MPEP at section 608.01(l), "[i]n establishing a disclosure, applicant may rely not only on the description and drawing as filed but also on the original claims if their content justifies it."

The Applicants respectfully submit that the written description requirement is met at least by the originally filed claims. The Applicants respectfully direct the Examiner's attention to the **originally filed claims** which provide evidence that the Applicants were in possession of the claimed invention at the time the application was filed.

For example, originally filed Claim 51 recites (emphasis added):

> 51. A method for conducting a hybridization assay within an enclosed hybridization chamber, comprising:

> (a) providing a device comprised of a (i) a substrate having a surface with at least a portion of said surface representing a hybridization region, wherein a plurality of oligonucleotide probes are bound to the substrate surface within the hybridization region and arranged in a spatially defined and physically addressable manner, and (ii) a cover which sealingly contacts the substrate surface about the hybridization region, wherein the cover and the hybridization region form an enclosure having an interior space comprising a hybridization chamber; and
>
> (b) introducing into the hybridization chamber a sample fluid comprising (i) a target molecule which may hybridize to a surface-bound molecular probe within the hybridization region, (ii) a hybridization buffer, and (iii) a surfactant of a type and present at a concentration effective to substantially reduce nonspecific binding and promote mixing of components within the sample fluid; and
>
> (c) maintaining hybridization conditions within the hybridization chamber for a period of time sufficient to allow hybridization between the target molecule and a surface-bound molecular probe to occur.

Accordingly, the originally filed claims provide an adequate written description that supports the breadth of scope of the claims as they pertain to the concentration of surfactant and as they pertain to the device.

Furthermore, the Applicants direct the Examiner's attention to the **Summary of the Invention** section of the application that also provides an adequate written description that supports the breadth of scope of the claims as they pertain to the concentration of surfactant and to the device. For example, the specification teaches (emphasis added):

> In a first embodiment, an apparatus is provided for use in conducting a chemical or biochemical reaction on a solid surface within an enclosed chamber, wherein the apparatus comprises:
>
> a substrate having a substantially planar surface with at least a portion of the surface representing a reaction area on which chemical or biochemical reactions are conducted;
>
> a plastic cover having a peripheral lip which sealingly contacts the substrate surface about the reaction area, wherein the cover and the reaction area form an enclosure having an interior space comprising a reaction chamber;
>
> a fastening means for immobilizing the cover on the substrate surface and providing a temporary, watertight seal between the cover and the reaction area; and
>
> a means for introducing fluid into the reaction chamber.

> In a related embodiment, a method is provided for conducting a hybridization assay within an enclosed hybridization chamber, wherein the method involves:
>
> (a) providing a device comprised of a (i) a substrate having a surface with at least a portion of said surface representing a hybridization region, wherein a plurality of molecular probes are bound to the substrate surface within the hybridization region and arranged in a spatially defined and physically addressable manner, and (ii) a cover which sealingly contacts the substrate surface about the hybridization region, wherein the cover and the hybridization region form an enclosure having an interior space comprising a hybridization chamber;
>
> (b) introducing into the hybridization chamber a sample fluid comprising (i) a target molecule which may hybridize to a surface-bound molecular probe within the hybridization region, (ii) a hybridization buffer, and (iii) a surfactant of a type and present at a concentration effective to substantially reduce nonspecific binding and promote mixing of components within the sample fluid; and
>
> (c) maintaining hybridization conditions within the hybridization chamber for a period of time sufficient to allow hybridization between the target molecule and a surface-bound molecular probe to occur.

Accordingly, the specification at least at the Summary of the Invention provides an adequate written description that supports the breadth of scope of the claims as they pertain to the concentration of surfactant and as they pertain to the device.

The Examiner points to particular passages in the application relating to exemplary surfactant concentrations (page 15) and device dimensions (page 13) and concludes that such passages limit the surfactant concentrations and device dimensions that may be claimed to those that are taught in the specific passages of pages 13 and 15. However, as described above, the specification clearly provides support for embodiments that are not limited to the concentrations described as exemplary embodiments and are not limited to the device dimensions described as exemplary embodiments (see for example the originally filed claims and the Summary of the Invention). For example, as noted above, the specification teaches a surfactant is present at a concentration effective to substantially reduce nonspecific binding and promote mixing of components within the sample fluid.

Furthermore, the passage cited by the Examiner describes *exemplary* embodiments of the subject invention. For example, in regards to the passage describing exemplary surfactant concentrations, the passage states "The surfactant **generally** represents between about..." In fact, the cited passage explicitly teaches that "**it should be emphasized that the exact concentration will vary with the surfactant selected, and those skilled in the art may readily optimize**

concentration with respect to the desired result." (emphasis added) The Examiner underlined the sentence "An exemplary sample fluid will contain between about 0.1 wt.% and about 1 wt.% of polyethylene oxide..." However, this sentence explicitly states that such is an **exemplary** fluid sample.

Likewise with respect to the dimensions of the device, as described above the specification clearly provides support for embodiments that are not limited to the exemplary dimensions taught on page 13, for example the originally filed claims and the Summary of the Invention. Furthermore, the passages cited by the Examiner describe exemplary embodiments of the subject invention. For example, the passage cited by the Examiner states that "This chamber height may range from...", indicating that the height merely may have such ranges, but may not.

As noted in the MPEP, there are certain situations in which an omission of a limitation or feature of a claim may support a rejection based on a lack of written description on the grounds that the inventor did not have possession of a broader, more generic invention (see for example MPEP section 2163.05 (I)). In such cases, as described in the MPEP, the specifications at issue made crystal clear that a particular understanding of a claim term is an essential element of the inventor's invention. This type of situation is clearly not analogous in any manner to the subject case; as noted above the instant specification in fact makes crystal clear that the ranges of concentrations of surfactant are exemplary only.

For example, In *The Gentry Gallery, Inc. v. The Berkline Corp.*, 134 F.3d 1473, 1479-80, 45 USPQ2d 1498, 1503 (Fed. Cir. 1998), described at 2163.05 of the MPEP, the Federal Circuit held claims to a sectional sofa that included a console and a pair of control means, were invalid for failing to satisfy the written description requirement in that the claims were broadened by removing language limiting the location of the control means to the console. **The court acknowledged that while a claim may be broader than the specific embodiment** disclosed in the specification, the "claims may be no broader than the supporting disclosure." (emphasis added) In *Gentry*, the court's holding of a lack of an adequate written description to support the claims at issue was based on *clear* statements in the written description that described the location of the 'control means' as 'the only possible location' and that variations were 'outside the stated purpose of the invention.' Accordingly, unlike the Applicants' specification which makes clear that the ranges described in the specification are exemplary only and which also specifically describes that the surfactant is present at a concentration effective to substantially reduce nonspecific binding and promote mixing of components within the sample fluid, in *Gentry* the patent's disclosure makes crystal clear that a particular (i.e., narrow) understanding of a claim term is an essential element of invention. (see also

Tronzo v. Biomet, 156 F.3d at 1158-59, 47 USPQ2d at 1833 (Fed. Cir. 1998) and *In re Wilder*, 736 F.2d 1516, 222 USPQ 369 (Fed. Cir. 1984)).

As described above, independent Claim 51 has been amended to specify the dimensions of the device, namely that the device has a height dimensions that is less than about 0.5 mm. While not acquiescing to the propriety of the rejection, the Applicants believe the amendments to Claim 51, in view of the above, obviate the rejection of Claim 51 and the claims that depend therefrom, under 35 U.S.C. §112, first paragraph.

For at least the reasons described above, the Applicants respectfully submit that the claims are adequately supported by the original disclosure and that the disclosure reasonably suggests that the Applicants were in possession of the claimed invention at the time of filing. Accordingly, the Applicants respectfully request this rejection be withdrawn.

REJECTION UNDER 35 U.S.C. §103

Claims 51-67 and 72-78 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Schnipelsky et al., or Zander et al, in view of Lipshutz et al., Wilding et al., and Livak et al.

With respect to independent Claim 51, and the claims that depend therefrom, the claims have been amended to specify that the device has a height dimensions that is less than about 0.5 mm. Accordingly, in order to render the claims obvious, the cited references must teach or suggest a method as claimed in Claim 51, namely a method that includes a chamber having a height dimension that is less than about 0.5 mm and a step of mixing fluid in the chamber using a bubble and a surfactant of a type and present at a concentration effective to promote mixing of components of a fluid introduced into the chamber and to substantially reduce nonspecific binding.

The cited references fail to teach or suggest a method as claimed in Claim 51. For example, the cited references fail to teach or suggest a device as claimed in Claim 51 that includes a chamber having a height dimension that is less than about 0.5 mm. Furthermore, the cited references fail to teach or suggest a step of mixing components of a fluid in such a dimensioned chamber using a bubble and a surfactant of a type and present at a concentration effective to promote mixing of components of a fluid introduced into the chamber and to substantially reduce nonspecific binding.

Furthermore, with respect to Claims 75 and the claims that depend therefrom, the Examiner has not pointed to any description in any of the cited references that teaches or suggests the method as claimed which is generally directed to a method of using a reusable hybridization cover. Specifically, Claim 75 specifies sealingly contacting a cover to a first substrate having a plurality of probes to form a first sealed hybridization chamber, performing a hybridization assay with this first

sealed chamber; opening the chamber and removing the first substrate and reusing the cover with a second substrate having a plurality of probes in a manner analogous to use with the first substrate. Such a method is not taught or suggested in the cited references. If this rejection is to be maintained, the Applicants respectfully request the Examiner to direct the Applicants to exactly where in the cited references a method as claimed in Claim 75 is described.

Accordingly, for at least the reasons described above, the cited references do not render the subject claims obvious. As such, the Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

In view of the remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-1078, reference no. 10990631-2.

Respectfully submitted,

Date: 6/2/04

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